## REMARKS

### I. Disposition of Claims

Claims 13 and 17 and 27 are currently pending. Claims 14-16 and 18-26 are canceled. Claim 13 and 17 are amended. These amendments are supported throughout the specification, for example in the original claims. Support for "a medical or experimental material" can be found, for example, on page 20, lines 15-17, and page 21, lines 15-16. Support for the limitation "in need of protection from said adverse effects" can be found, for example, on page 2, lines 15-16, page 39, line 4-18. New Claim 27 is submitted. Support for the new claim can be found on page 33, line 17-page 34, line 1. No new matter is added.

### II. Specification

The Examiner has required that the Specification be amended so that all trademarks are properly identified as such. The Specification has been amended so that all trademarks are written in capital letters and accompanied with generic terminology for each product.

### III. Written description

The Examiner has rejected the claims 13-26 under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

#### A. "Determining"

Specifically, the Examiner asserted that the step of "determining that a subject will be exposed to 10 kGy or more of said x-rays, gamma rays and/or electron beams" is not supported in the specification.

According to MPEP 2163: "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention."

With the present amendment, Applicant has deleted the term "determining" and incorporated the exposure of 10 kGy or more of the radiation into the preamble of claim 13. Furthermore, the applicant added "in need of protection from said adverse effects" language to the claim. Such language is supported in *Jansen v. Rexall Sundown Inc.*, 68 USPQ2d 1154 (Fed. Cir. 2003), wherein the court considered the validity of the following claim:

> 1. A method of treating or preventing macrocytic-megaloblastic anemia in humans which anemia is caused by either folic acid deficiency or by vitamin $B_{12}$

deficiency which comprises administering a daily oral dosage of a vitamin preparation to a human **in need thereof** comprising at least 0.5mg of vitamin $B_{12}$ and at least 0.5 mg of folic acid.

The court ruled that claims for a method of "treating or preventing" pernicious anemia by administering folic acid and vitamin $B_{12}$ "to a human in need thereof" are properly construed to require that the compound be administered to human with recognized need to treat or prevent anemia (first paragraph). As the current claim as amended parallels this claim construction, the current claim can be construed to require covering a material with recognized need to avoid the adverse effects recited in the preamble.

In view of the amendments, the rejection with regard to a "determining" step should be withdrawn.

**B. "10 kGy"**

Further, the Examiner asserted that the meaning of "10 kGy" without specifying the amount (mass) of the subject and the length of time is inchoate. Applicant has amended the claim so as to limit the subject that is exposed to radiation to a medical or experimental material. One of skill in the art can take into account the mass of the material, the length of time of exposure to radiation during medical or experimental use, and the environment surrounding the medical or experimental material to determine the total exposure. Therefore, one of skill in the art would understand that the inventor was in possession of the claim at the time of filing, and the rejection should be withdrawn.

**C. "10kGy or more"**

Regarding the phrase "10 kGy or more" in Claim 13, the Examiner asserted that there is no support for the phrase "or more". Again the standard according to MPEP 2163 is that to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." Experiments 3 and 4 (pages 35-38) of the specification clearly show the blocking or reducing of adverse effects on an experimental material, i.e., alpha amylase, when the experimental material is exposed to 10 kGy of the radiation of X-rays, electron beams or gamma rays. It is generally accepted that the adverse effects of radiation increase linearly as exposure increases. Thus, any shielding that provides a measure of protection at a lower level of exposure will provides a substantially equal level of protection when exposure is increased. That is, the shielding does not become any less valuable

simply because the rate of exposure increases. Based on the results of experiments 3 and 4 of the specification, one who is skilled in the art would be led to perceive that sufficient actions for blocking or reducing the adverse effects on an experimental material could also be achieved in the case of any radiation of more than 10 kGy.

**D. Correlation Based on a-Amylase Activity**

Further, the Examiner asserted that there is no disclosure or evidence of record that the reduction of a-amylase activity correlates or corresponds to evidence that humans or inanimate objects can be protected from similar exposures.

As shown above, we have limited the subject that is exposed to radiation to the medical or experimental material that is used in experiments 3 and 4 of the specification. Moreover, The effects of radiation on amylase activity has been used as an experimental model for evaluating the effects of radiation exposure for many years, as it is a very sensitive system (see Thompson and Hussey, 1931, The Effect of Radiation from a Mercury Arc in Quartz on Enzymes, J. Gen. Physilogy, Vol 15, pages 9-13) estimated to be 50 times more sensitive that a similar assay using pepsin solutions (page 12, last full paragraph). Therefore, the above rejection should be overcome by this amendment.

**IV. Definiteness**

**A. Claim 17**

The Examiner has rejected Claim 17 under 35 USC 112, second paragraph, as being indefinite due to an unclear antecedent bases for the "subject". The Claim has been amended to address this issue, so the rejection should be withdrawn.

**B. Claims 17 and 24**

The Examiner has rejected Claims 17 and 24 under 35 USC 112, second paragraph, as being indefinite, because it was unclear to the Examiner what noun the "0.05 wt% to 40 wt%" refers to. Claim 24 has been canceled. Claim 17 has been amended to clarify this issue, and so the rejection should be withdrawn.

**V. Utility**

The Examiner has rejected Claims 16, 17, 23 and 24 under 35 USC 101 for lack of Utility. The Examiner asserts that it "flies in the face of reason" that the subject could be protected by using a shield inside the subject. Claim 16, 23 and 24 have been canceled. Claim

17 has been amended to remove language related to the inside of a subject. Therefore, the rejection should be withdrawn.

**VI. Non-Obviousness**

The Examiner has rejected Claims 20-26 under 35 USC 103(a) as being obvious over Talty ("Industrial Hygene Engineering - Recognition, Measurement, Evaluation and contol (2nd Ed)"). Claims 20-26 have been canceled, therefore the rejection is moot.

**CONCLUSION**

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 3-26-2007

By: 

Eric Ives
Registration No. 50,928
Agent of Record
Customer No. 20,995
(805) 547-5580

AMEND

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# THE EFFECT OF RADIATIONS FROM A MERCURY ARC IN QUARTZ ON ENZYMES

## II. The Effect of Ultra-Violet Radiation on Amylase in Solution

By WILLIAM R. THOMPSON and RAYMOND HUSSEY

*(From the Department of Pathology, Yale University, New Haven)*

(Accepted for publication, June 12, 1931)

In an earlier report[1] we have given the results of experiments which are concerned with the effects of irradiation of solutions of pepsin with ultra-violet light, wherein these results were compared with similar effects of irradiation with radiations from radon and its radioactive products in dynamic equilibrium with it, wherein also were included studies with other enzymes, namely, trypsin and invertase. Under fixed conditions of irradiation, it was shown that inactivation of the enzyme took place in each instance studied and that the relation between the enzyme concentration, $Q$, after irradiation and that before irradiation, $Q_o$, could be approximated closely in all cases by the relation,

$$Q = Q_o \cdot e^{-k \cdot W} \tag{1}$$

where $W$ is a variable proportional to the radiant energy liberated by the source of radiation during the irradiation interval, and $k$ is a positive constant (dependent in each case upon the enzyme system used and upon the conditions of irradiation aside from those which determine the power of the source and period of irradiation). Where the power of the source is constant (or approximately so) then the time, $t$, of irradiation may be substituted for $W$ in (1) in the general sense there employed, though it should be borne in mind that if a fixed energy unit system for $W$ in a given case has been adopted, as, for example, in the case of the $\beta$-ray experiments previously reported,[2]

[1] Hussey, R., and Thompson, W. R., *J. Gen. Physiol.*, 1925–26, 9, 217.

[2] Hussey, R., and Thompson, W. R., *J. Gen. Physiol.*, 1922–23, 6, 7.

then a change to a proportional variable in place of $W$ should be accompanied by a change in the value of $k$ in inverse proportion. In the case of ultra-violet irradiation of pepsin, wherein the power of the source (a mercury arc in quartz) might be assumed, if not constant, at least to fluctuate so that $t$ is approximately proportional to the energy liberated under the existing conditions of irradiation, we have shown a satisfactory fit of the results obtained to the relation

$$Q = Q_0 \cdot e^{-k \cdot t}; \tag{2}$$

or, in differential form,

$$\frac{dQ}{dt} = -k \cdot Q \quad \text{or} \quad \frac{d \log Q}{dt} = -k, \tag{3}$$

which obviously implies a linear relation between the logarithm of the enzyme concentration and the duration of irradiation under such conditions; or, in general, with the variable $W$.

Recently, we have been concerned in this laboratory with the estimation of active amylase concentration by means of a viscosimetric method described in another communication[3] a modification of which is suggested in another report[4] from this laboratory by Wies and McGarvey. By means of this modified method we have studied the effects of radiations from a mercury arc in quartz upon amylase solutions.

## EXPERIMENTAL PROCEDURES

The solutions were prepared from pancreatin in 0.85 per cent saline as previously described,[3,4] and the irradiation system was essentially the same as that previously employed in the experiments[1] with pepsin mentioned above. Enzyme was irradiated in the same flat bottomed cylindrical quartz tube (about 25 mm. inside diameter, 1 mm. in thickness, and 36 mm. long) placed vertically above a quartz window (approximately 3 mm. thick and 25 mm. in diameter) in the bottom of a thermoregulated water bath at 10.0 ±.15°C., the water of which was freshly distilled (being replaced at least once every 3 days). The same mechanical stirring device was employed to agitate the enzyme solution during irradiation for which the same mercury arc was employed, tilted at a fixed angle

[3] Thompson, W. R., Johnson, C. E., and Hussey, R., *J. Gen. Physiol.*, 1931–32, 15, 1.

[4] Wies, C. H., and McGarvey, S. M., unpublished.

of 30° to the horizontal, and in a position about 19.0 cm. vertically beneath the quartz window of the bath. The amount of enzyme solution irradiated in the present experiments was 5 ml. A control portion of the same enzyme solution was kept in the same bath in a light-screened container.

The results of a number of such irradiations are given in Table I. Successive estimations upon the control solution showed that the rate of spontaneous inactivation was negligible with respect to the rate of the radiochemical change. Accordingly, $Q_o$ is taken in each instance as the concentration of amylase in the control solution at the end of the irradiation interval. Precise estimates of the rate of spontaneous inactivation of amylase under the control conditions are not available, but it is estimated as about 10 per cent per day; and this is obviously

TABLE I

| $t$ (min.) | $Q_o$ | $Q$ | $\frac{Q}{Q_o}$ | $k'$ (min.)$^{-1}$ | $k' - k$ |
|---|---|---|---|---|---|
| 1.03 | 10.45 | 8.60 | 0.823 | 0.189 | −0.049 |
| 2.00 | 10.85 | 6.52 | 0.601 | 0.255 | +0.017 |
| 4.00 | 9.66 | 3.85 | 0.399 | 0.230 | −0.008 |
| 6.00 | 12.64 | 3.14 | 0.248 | 0.232 | −0.006 |
| 9.00 | 12.11 | 1.38 | 0.114 | 0.241 | +0.003 |

Taking the approximation, $k = 0.238$ min.$^{-1}$

negligible in the present experiments with respect to a radiochemical change of about 50 per cent in 3 minutes as observed (approximately 3000 times as great). In Table I will be found the corresponding values of $t$, $Q_o$, $Q$, and $\frac{Q}{Q_o}$ for each irradiation, together with $k'$—defined as the value of $k$ calculated in each such instance from the formula of (2). The value of $k$ obtained by fitting the curve given by

$$\log \frac{Q}{Q_o} - k \cdot t = 0 \tag{4}$$

to the observed points, $(\log \frac{Q}{Q_o}, t)$, by the method of least squares was found to be 0.2376 min.$^{-1}$. The differences between 0.238 and the observed values of $k'$ are given in the same table, where it may be

seen that they decrease in *absolute* value with increase in $t$, as might be expected.

It may be noted, furthermore, that inactivation has been extended as far as 88 per cent change, approximately. In order to estimate $Q$ in such cases of great change, a flexibility of the viscosimetric method previously described was utilized by replacement of the usual addition of 5 ml. of enzyme to 25 ml. of substrate solution (3 per cent starch substrate) by the addition instead of first $x$ ml. of 0.85 per cent saline and then $y$ ml. of enzyme solution (where $x + y = 5$) to the above amount of substrate. $Q$ is calculated from the resulting value of $T$ (the time in hours for 15.8 per cent change in viscosity as described[4]) for the given digestion curves by the formula

$$Q = \frac{5}{y \cdot T}. \tag{5}$$

## DISCUSSION

In the earlier work[1] upon the effects of ultra-violet radiation upon pepsin in solution it was observed in two successive experiences that, although the relation (2) held, it was necessary to introduce different constants for $k$ in each instance. This was supposed to be due to a decrease in the intensity of radiation incident to the irradiated solution. Care was taken in the present experiments as to elimination of and prevention of accumulation of impurities in the water which might induce such decrease in intensity of radiation. The consistent results obtained indicate that the required condition of sensibly constant ratio between the time of irradiation, $t$, and the energy increment was realized. However, in subsequent work temporary deviations were noted which may be due to variation in the potential difference of the lamp electrodes. Further work in this connection is in progress.

Direct comparison of sensitivity of pepsin and amylase solutions is made impossible in these results due to the lack of definite information as to radiation intensities, but it seems evident that amylase solutions are much more sensitive than are pepsin solutions, perhaps more than 50 times as sensitive.

Further work involving different aspects of the radiochemical

inactivation of amylase is in progress in this laboratory, one of the immediate results of which is a demonstration that sensibly complete protection (within the limits of tolerance of the present work) is given by interposition of a No. 1 Crookes Glass filter (1.7 mm. thick) between the quartz window and the enzyme solution.

SUMMARY

Amylase in solution is inactivated by the radiations from a mercury arc in quartz, in a manner similar to that previously reported for pepsin. The reaction was followed to a point where more than 88 per cent change had taken place, the course being that of monomolecular radiochemical change. Apparently, this reaction is due to the influence of ultra-violet radiation alone.

of its affirmative defenses relating to the non-infringement of the '774 and '109 patents.[7] This sanction is the only one appropriate to deter Waterloo from future misconduct while at the same time protecting Ciba and adequately remedying its harm. The effect of this remedy is a finding that Waterloo infringed Ciba's patent, leaving only the issue of damages to be resolved by this Court.

Ciba also moves the Court for attorneys fees and costs. "[T]he 'less severe sanction' of an assessment of attorney's fees is undoubtedly within a court's 'inherent power . . .' *Chambers*, 501 U.S. at 45. Accordingly, the Court also permits Ciba to file an application for attorneys' fees and for any additional costs incurred as a result of this fraud upon the court.

*IV.*

For the foregoing reasons, Plaintiff's Motion Expedited Conference on Defendants' Apparent Fraud Upon the Court (Doc. #26), construed herein as a Motion for Sanctions, is *GRANTED*. The Court *STRIKES* Defendant Waterloo's affirmative defenses and dismisses its counter-claims.[8]

*IT IS SO ORDERED.*

*ORDER*

On *AUGUST 28, 2003 at 10:00 A.M.*:

*MR. DENTON BOWMAN* shall appear and show cause why he should not be held in contempt for perpetrating a fraud upon this Court. The Court urges Mr. Bowman to retain his own counsel. Although he testified that he is the Executive Vice President of Waterloo Coal Company, nonetheless, if Mr. Bowman contends that he does not have sufficient financial resources to retain his own independent counsel, he shall so notify the Court in writing within ten (10) days of the date of this Order. If Mr. Bowman provides such written notification, the Court will consider appointing an attorney for him for purposes of this Show Cause Hearing.

*IT IS SO ORDERED.*

[7] The Court does not by this ruling pass on the validity or enforceability of the '774 or '109 patents. *See Aptix Corp. v. Quickturn Design Sys.*, 269 F.3d 1369 [60 USPQ2d 1705] (Fed. Cir. 2001) (holding that courts are free to sanction bad faith conduct but may not invalidate the patent as part of sanction).

[8] Because Plaintiff has not suggested and no evidence presented at the hearing supports the conclusion that either of the two remaining Defendants participated in the fraud, this matter will proceed to hearing with respect to Defendants Zinkan Enterprises, Inc. and Hubert Fairchild, Jr.

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**Jansen v. Rexall Sundown Inc.**

**U.S. Court of Appeals**
**Federal Circuit**

No. 03-1069

Decided September 8, 2003

**PATENTS**

**[1] Patent construction — Prosecution history estoppel (§ 125.09)**

**Patent construction — Claims — Broad or narrow (§ 125.1303)**

Claims for method of "treating or preventing" pernicious anemia by administering folic acid and vitamin $B_{12}$ "to a human in need thereof," are properly construed to require that compound be administered to human with recognized need to treat or prevent anemia, since "treating or preventing" phrase in preambles sets forth objective of claimed method, and body of claim directs that method be performed on subject "in need," and since prosecution history supports this construction, in that patentability hinged upon addition of phrases to claim language, and phrases were added simultaneously, and should be read together; thus, claimed method is not practiced if claimed vitamins in claimed doses are administered for some purpose other than treating pernicious anemia.

**[2] Infringement — Construction of claims (§ 120.03)**

**Infringement — Literal infringement (§ 120.05)**

Federal district court properly granted summary judgment that administration of defendant's over-the-counter dietary supplement does not infringe claimed method of "treating or preventing" pernicious anemia by administering folic acid and vitamin $B_{12}$ "to a human in need thereof," even though amounts of folic acid and vitamin $B_{12}$ in accused supple-

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Construction of claims

Literal infringement

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ment are within ranges claimed in patent, since asserted claims are properly construed to require that compound be administered to human with recognized need to treat or prevent anemia, since, without evidence that accused product is prescribed by medical doctors, plaintiff has shown no more than theoretical possibility that defendant's customers take accused product knowingly to treat pernicious anemia, and since such "metaphysical doubt" is insufficient to raise genuine issue of material fact.

**Particular patents — Chemical — Vitamins**

4,945,083, Jansen, safe oral folic-acid-containing vitamin preparation, summary judgment of noninfringement affirmed.

Appeal from the U.S. District Court for the Southern District of Indiana, Tinder, J.

Action by Christian J. Jansen Jr. against Rexall Sundown Inc. for contributory patent infringement and inducement. Plaintiff appeals from summary judgment of noninfringement. Affirmed.

John C. McNett and Steve E. Zlatos, of Woodard, Emhardt, Naughton, Moriarty & McNett, Indianapolis, Ind., for plaintiff-appellant.

Gary H. Levin and Lynn B. Morreale, of Woodcock Washburn, Philadelphia, Pa., for defendant-appellee.

Before Lourie, Rader, and Schall, circuit judges.

**Lourie, J.**

Christian J. Jansen, Jr., appeals from the final decision of the United States District Court for the Southern District of Indiana granting summary judgment that Rexall Sundown, Inc. has not infringed Jansen's U.S. Patent 4,945,083. *Jansen v. Rexall Sundown, Inc.*, No. IP 00-1495-C-T/G (S.D. Ind. Sept. 25, 2002). Because the court correctly construed the patent claims and correctly found no genuine issues of material fact on the question of infringement, we affirm.

## BACKGROUND

Jansen is the sole inventor and owner of the '083 patent, which is directed to methods of "treating or preventing macrocytic-megaloblastic anemia" by administering a combination of folic acid and vitamin $B_{12}$ "to a human in need thereof." '083 patent, col. 6, ll. 20-24; ll. 37-41. According to the patent, deficiencies of either folic acid or vitamin $B_{12}$ can cause macrocytic-megaloblastic anemia, also referred to as pernicious anemia, while a deficiency of vitamin $B_{12}$ can also cause neurological problems. *Id.* at col. 4, ll. 13-25. When folic acid alone is utilized to treat macrocytic-megaloblastic anemia, the folic acid may mask a vitamin $B_{12}$ deficiency. *Id.*; *see also id.* at col. 3, l. 65 – col. 4, l. 5. An objective of Jansen's invention is to administer both supplements together to avoid the masking problem. *Id.* at col. 4, ll. 25-48. The independent claims read as follows:

> 1. A method of *treating or preventing macrocytic-megaloblastic anemia* in humans which anemia is caused by either folic acid deficiency or by vitamin $B_{12}$ deficiency which comprises administering a daily oral dosage of a vitamin preparation *to a human in need thereof* comprising at least about 0.5 mg. of vitamin $B_{12}$ and at least about 0.5 mg. of folic acid.
>
> 4. A method of *treating or preventing macrocytic-magaloblastic [sic] anemia* in humans which anemia is caused by either folic acid deficiency or by vitamin $B_{12}$ deficiency which comprises orally administering combined vitamin $B_{12}$ and folic acid *to a human in need thereof* in sufficient amounts to achieve an oral administration of at least about 0.5 mg. of vitamin $B_{12}$ and at least about 0.5 mg. of folic acid within one day.

*Id.* at col. 6, ll. 20-24, ll. 37-41 (emphases added).

The '083 patent is a seventh-generation continuation of a patent application filed in 1970. Every member of the '083 patent's lineage was abandoned in favor of the succeeding application until the '083 patent issued in 1990. Jansen's first application claimed the method as follows:

> A method of treating or preventing anemia in humans which comprises administering a daily oral dosage of a vitamin preparation containing at least .5 mg. of vitamin $B_{12}$ and at least .5 mg. of folic acid, whereby anemia can safely be treated orally without determining whether it is caused by folic

acid deficiency or by vitamin $B_{12}$ deficiency.

*In re Jansen*, 187 USPQ 743, 744 (CCPA 1975). That original claim, while specifying approximately the same amounts of folic acid and vitamin $B_{12}$, does not specify the type of anemia being treated and says nothing about any need on the part of the human subject. The U.S. Patent and Trademark Office ("PTO") found that claim, as well as claims directed to the composition of matter, to be obvious in light of prior art that taught administration of folic acid alone in the claimed range, vitamin $B_{12}$ alone in the claimed range, and combinations of the two in smaller doses than claimed. The PTO found unpersuasive Jansen's argument that administration of both components in the higher, claimed doses was an unexpected solution to the masking problem, and the Court of Customs and Patent Appeals affirmed the PTO's rejections. *Id.* at 746. In his next five applications, Jansen persistently attempted to gain allowance of his claims in slightly different form, yet the PTO consistently rejected his attempts. In the prosecution of his seventh application, Jansen repeated his masking-avoidance argument and submitted an article that asserted that the medical community had come to realize the effectiveness of folic acid-vitamin $B_{12}$ combination therapy to treat pernicious anemia only after Jansen's invention date. *See* William H. Crosby, *Improvisation Revisited—Oral Cyanocobalamin Without Intrinsic Factor for Pernicious Anemia*, 140 Arch. Intern. Med. 1582 (1980). The examiner agreed but noted that the claims, being directed to unspecified anemia, were not commensurate in scope with Jansen's showing of unexpected results. Jansen thereafter agreed to cancel his composition of matter claims and to narrow his method claims by requiring a specific type of anemia, viz., macrocytic-megaloblastic anemia, rather than anemia generally, and by adding to the claims the phrase "to a human in need thereof." The PTO then issued the '083 patent to Jansen.

Rexall markets to the general public an over-the-counter dietary supplement presently known as Folic Acid XTRA™ that contains folic acid and vitamin $B_{12}$ within the claimed ranges. The Rexall product is labeled and advertised for maintenance of proper blood homocysteine levels, but not for prevention or treatment of macrocytic-megaloblastic anemia.

Jansen sued Rexall for inducement of and contributory infringement of the '083 patent. In the district court Jansen argued that all people are "human[s] in need" of "treat[ment] or prevent[ion] of macrocytic-megaloblastic anemia," but the court, without definitively construing the "in need" phrase, rejected that argument. *Jansen*, slip op. at 14. Citing, *inter alia*, *Rapoport v. Dement*, 254 F.3d 1053 [59 USPQ2d 1215] (Fed. Cir. 2001), the court then construed the phrase "treating or preventing macrocytic-megaloblastic anemia" to require that, in order to infringe the patent, the human subject of the claimed method take the compound with the intent of treating or preventing macrocytic-megaloblastic anemia. *Jansen*, slip op. at 16. Because the court found no evidence of such intent or purpose on the part of Rexall's customers, the court granted summary judgment of noninfringement. *Id.* at 16-17.

Jansen timely appealed to this court, and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

## DISCUSSION

Summary judgment is appropriate if "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). "The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). We review a district court's grant of a motion for summary judgment *de novo*. *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 [47 USPQ2d 1272] (Fed. Cir. 1998).

A determination of patent infringement requires a two-step analysis. "First, the court determines the scope and meaning of the patent claims asserted . . . [Second,] the properly construed claims are compared to the allegedly infringing device." *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 [46 USPQ2d 1169] (Fed. Cir. 1998) (en banc) (citations omitted). Step one, claim construction, is an issue of law, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 [34 USPQ2d 1321] (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 [38 USPQ2d 1461]

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for inducement of and nent of the '083 patent. Jansen argued that all an[s] in need" of en[tion] of macrocytic-," but the court, without g the "in need" phrase, t. *Jansen*, slip op. at 14. *apoport v. Dement*, 254 2d 1215] (Fed. Cir. n construed the phrase eventing . . . macrocytic-" to require that, in or-atent, the human subject od take the compound treating or preventing astic anemia. *Jansen*, e the court found no evi-or purpose on the part of the court granted sum-minfringement. *Id.* at 16-

aled to this court, and we ursuant to 28 U.S.C.

## CUSSION

nt is appropriate if "there s to any material fact and r is entitled to a judgment " Fed. R. Civ. P. 56(c). e nonmovant is to be be-iable inferences are to be r." *Anderson v. Liberty* 5, 242, 255 (1986). We re-t's grant of a motion for *de novo*. *Ethicon Endo-Surgical Corp.*, 149 F.3d SPQ2d 1272] (Fed. Cir.

of patent infringement re-analysis. "First, the court ope and meaning of the ed . . . [Second,] the props are compared to the al-device." *Cybor Corp. v.* 138 F.3d 1448, 1454 [46 d. Cir. 1998) (en banc) (ci-ep one, claim construction, *Markman v. Westview In-*2 F.3d 967, 970-71 [34 ed. Cir. 1995) (en banc), 370 [38 USPQ2d 1461] (1996), that we review *de novo*, *Cybor*, 138 F.3d at 1456. Step two, comparison of the claim to the accused device, requires a determination that every claim limitation or its equivalent is found in the accused device. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 [41 USPQ2d 1865] (1997). Those determinations are questions of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 [48 USPQ2d 1674] (Fed. Cir. 1998).

On appeal, Jansen first argues that the court improperly construed the claims. More specifically, he contends that the court's construction improperly added to the claims an intent element, which is contrary to law as well as contrary to the ordinary meaning of the claim language, which does not suggest that the infringer's state of mind is relevant. Nor does the '083 patent's prosecution history, according to Jansen, suggest that the infringer's state of mind is relevant. He also argues that *Rapoport* does not support the court's view that a direct infringer must purposefully perform the claimed method, and that in any event *Rapoport* is distinguishable because that case, unlike this case, did not involve a claim to a method of prevention of a disease. According to Jansen, the phrase "a human in need thereof" encompasses a person who does not know that his or her serum levels of folic acid and vitamin $B_{12}$ are adequate. Jansen secondly argues that he presented sufficient evidence of infringement to avoid summary judgment. According to Jansen, Rexall's formulation and labeling are circumstantial evidence of direct infringement by Rexall's customers.

Rexall responds that the court's claim construction does not add an intent element to the claims except as required by the particular language of the claims themselves. Rexall also contends that, just as in *Rapoport*, the claims in the '083 patent should be interpreted to require that the target group ("human[s] in need thereof") practice the method for the stated purpose ("treating or preventing macrocytic-megaloblastic anemia"), especially where, as here, the prosecution history reveals that both limitations were added for patentability. According to Rexall, a "human in need thereof" is someone either suffering from macrocytic-megaloblastic anemia or at a recognized risk, such as by medical diagnosis, of developing that condition. Rexall also responds that there is no evidence that it markets its product to the target group for the claimed purpose; on the contrary, it contends that it markets its product only for regulation of blood homocysteine levels. Rexall further contends that even if there were some evidence of direct infringement by its customers, it is not liable for indirect infringement, for it has not intended to cause infringement and there are substantial noninfringing uses of its product, thereby negating inducement of and contributory infringement.

We begin our claim construction, as always, with the ordinary meaning of the claim language. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1341 [60 USPQ2d 1851] (Fed. Cir. 2001). That language requires that the method be performed on "a human in need thereof," and that the method be used "for treating or preventing macrocytic-megaloblastic anemia." The parties do not dispute what "macrocytic-megaloblastic anemia" means; instead, they dispute how the "treating or preventing" phrase and the "to a human in need thereof" phrase should be read. The issue reduces to whether such a human must know that he is in need of either treatment or prevention of that condition.

A similar issue arose in *Rapoport*, an interference proceeding before the PTO's Board of Patent Appeals and Interferences. The count in that case read as follows:

> A method *for treatment of sleep apneas* comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof *to a patient in need of such treatment*

254 F.3d at 1056 (emphases added). On appeal we gave weight to the ordinary meaning of the preamble phrase "for treatment of sleep apneas," interpreting it to refer to sleep apnea, *per se*, not just "symptoms associated with sleep apnea." *Id.* at 1059. Rapoport argued that the count was unpatentable on the ground that a prior art reference disclosed that a form of the compound recited in the claim could be administered, not for treatment of sleep apnea itself, but for treatment of anxiety and breathing difficulty, a symptom of apnea. *Id.* at 1061. We rejected that argument, stating, "There is no disclosure in the [prior art reference that the compound] is administered to patients suffering from sleep apnea *with the intent to cure the underlying condition*." *Id.* (emphasis added). Thus, the claim was interpreted to require that the method be practiced

with the intent to achieve the objective stated in the preamble.

[1] Just as in *Rapoport*, it is natural to interpret the nearly parallel language in the '083 patent claims in the same way. In both *Rapoport* and this case, the claim preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone "in need." In both cases, the claims' recitation of a patient or a human "in need" gives life and meaning to the preambles' statement of purpose. *See Kropa v. Robie*, 187 F.2d 150, 152 [88 USPQ 478] (CCPA 1951) (stating the rule that a preamble is treated as a limitation if it gives "life and meaning" to the claim). The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, it is a statement of the intentional purpose for which the method must be performed. We need not decide whether we would reach the same conclusion if either of the "treating or preventing" phrase or the "to a human in need thereof" phrase was not a part of the claim; together, however, they compel the claim construction arrived at by both the district court and this court.

Our conclusion as to the meaning of the claims is bolstered by an analysis of the prosecution history. The prosecution history is often useful to ascertain the meaning of the claim language. Indeed, claims are not construed in a vacuum, but rather in the context of the intrinsic evidence, *viz.*, the other claims, the specification, and the prosecution history. *See DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1327 [57 USPQ2d 1889] (Fed. Cir. 2001). In this case, the "treating or preventing macrocytic-megaloblastic anemia" phrase and the "to a human in need thereof" phrase were added to gain allowance of the claims after almost twenty years of repeatedly unsuccessful attempts to gain allowance of claims without those phrases. We must therefore give them weight, for the patentability of the claims hinged upon their presence in the claim language. *See Smith v. Magic City Kennel Club, Inc.*, 282 U.S. 784, 790 (1931) ("The applicant[,] having limited his claim by amendment and accepted a patent, brings himself within the rules that if the claim to a combination be restricted to specified elements, all must be regarded as material, and that limitations imposed by the inventor, especially such as were introduced into an application after it had been persistently rejected, must be strictly construed against the inventor and looked upon as disclaimers."). Furthermore, because both phrases were added simultaneously to overcome the same rejection, they should be read together, meaning that the word "thereof" in the phrase "to a human in need thereof" should be construed to refer to the treatment or prevention of macrocytic-megaloblastic anemia. Finally, that "need" must be recognized and appreciated, for otherwise the added phrases do not carry the meaning that the circumstances of their addition suggest that they carry. In other words, administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megaloblastic anemia is not practicing the claimed method, because Jansen limited his claims to treatment or prevention of that particular condition in those who need such treatment or prevention. Thus, the '083 patent claims are properly interpreted to mean that the combination of folic acid and vitamin $B_{12}$ must be administered to a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia.

[2] Given that claim construction, we turn to the issue whether Jansen has raised a genuine issue of material fact regarding infringement. We conclude that he has not. Jansen has asserted indirect infringement by Rexall, premised on direct infringement by Rexall's customers. *See Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 [231 USPQ 474] (Fed. Cir. 1986) ("Absent direct infringement of the patent claims, there can be neither contributory infringement nor inducement of infringement." (citations omitted)). Jansen's theory of infringement is primarily based upon his construction of the claim that those who do not affirmatively know that they do not need to take steps to prevent or treat macrocytic-megaloblastic anemia are still "in need thereof." As explained above, that claim construction is incorrect. Jansen nonetheless asserts that he has circumstantial evidence of direct infringement by Rexall's customers under the claim construction we and the district court have adopted. Specifically, he contends that Rexall's formulation, having folic acid and vitamin $B_{12}$ in such large quantities as his claims call for, as well as Rexall's labeling stating that "[i]t is especially important to take B-12 along with Folic acid because Folic

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acid can mask a B-12 deficiency," are evidence that some customers do knowingly take the Rexall product to treat or prevent macrocytic-megaloblastic anemia.

While Jansen is correct that it is theoretically possible that some of Rexall's customers do take the Rexall product knowingly to treat or prevent macrocytic-megaloblastic anemia, and therefore directly infringe his patent, his evidence is quite weak. In fact, he has shown no more than a theoretical possibility or "metaphysical doubt," which is insufficient to create a *genuine* issue of material fact. *See Anderson*, 477 U.S. at 261 (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986)). The district court's decision that there were no genuine issues of material fact on the question of infringement was therefore correct.

Use of an over-the-counter product like Rexall's is quite different from the use of a product pursuant to a prescription from a medical doctor. In the latter case, a prescription is evidence of a diagnosis and a knowing need to use the product for the stated purpose. Jansen does not have evidence of that in this case. Rexall's product is provided with a label stating that the product can be used for maintenance of blood homocysteine levels, and purchasers do not necessarily know that they are in need of preventing or treating macrocytic-megaloblastic anemia. Instead, Jansen has only conjecture that some purchasers of the Rexall product might meet the claim requirements. The district court therefore did not err in holding that he failed to present sufficient proof of infringement to create a genuine issue of material fact and to thereby avoid summary judgment of noninfringement.

## CONCLUSION

The district court correctly construed the claims of the '083 patent and properly determined that Jansen did not present sufficient evidence to create a genuine issue of material fact relating to infringement by Rexall. Accordingly, we

*AFFIRM.*

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## Droz-Serrano v. Caribbean Records Inc.

U.S. District Court
District of Puerto Rico
No. 03-1114 (JAG)
Decided June 24, 2003

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**[1] Infringement pleading and practice — Jurisdiction (§ 217.05)**

JUDICIAL PRACTICE AND PROCEDURE

**Jurisdiction — Subject matter jurisdiction — Federal question (§ 405.0702)**

Federal district court lacks subject matter jurisdiction over plaintiff recording artist's action for breach of recording and management agreements, even though subject matter of agreements is copyrighted material, since action does not "arise under" federal copyright laws merely because it relates to product that is subject of copyright, since examination of pleadings clearly shows that present action is strictly contract dispute, and since Copyright Act need not be construed in case in which plaintiff's sole remedy is action for contract damages.

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Action by Yesenia Droz-Serrano against Caribbean Records Inc. and Maritza Casiano for breach of recording and management agreements, and failure to pay royalties. On defendants' motion to dismiss for lack of jurisdiction. Granted.

Jose R. Franco-Rivera, San Juan, P.R., for plaintiff.

Edwin Prado-Galarza, San Juan, for defendants.

**Garcia-Gregory, J.**

Pending before this Court is defendants' motion to dismiss for lack of jurisdiction (Docket No. 5), as well as plaintiff's opposition to the motion (Docket No. 8). For the reasons discussed below, this Court GRANTS defendants' motion to dismiss.

### *Facts*

Plaintiff in this action, Yesenia Droz-Serrano ("Droz") is a recording artist who